



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : PAWELEK, et al.

U.S. Serial No.: 10/723,570, a continuation of U.S. Serial No. 09/358,052, filed July 21, 1999, now U.S. Patent No. 6,685,935, issued February 3, 2004, which is a continuation of U.S. Serial No. 08/658,034, filed June 4, 1996, now U.S. Patent No. 6,190,657, issued February 20, 2001, which is a continuation-in-part of U.S. Serial No. 08/486,422, filed June 7, 1995, now abandoned

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For : VECTORS FOR THE DIAGNOSIS AND TREATMENT OF SOLID TUMORS INCLUDING MELANOMA

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3/24/2006

JD

AFFIDAVIT UNDER 37 CFR 1.132

My name is David Bermudes. I have BA in Biology from Oberlin College and a Ph.D. in Cell and Molecular Biology from Boston University. I am currently employed at Vion Pharmaceuticals as Director of Microbiology. I have 12 years of experience in the field of microbial pathogenesis and genetic engineering of bacteria.

I wish to affirm to the ability of one ordinarily skilled in the arts to construct an *E. coli* strain according to the invention for inhibiting the growth of a solid tumor cancer, comprising administering to a patient having a solid tumor; a tumor specific *Escherichia coli* genetically engineered to express a suicide gene. The embodiments we described using *Salmonella*, although novel and non-obvious, was merely exemplary and, thus, extrapolation to use *E. coli* would not require *undue* experimentation for one of ordinary skill in the art due to the known biological similarities of *E. coli* with *Salmonella*. The strong similarities were noted Riley and Krawiec in 1987 Chapter 56. Genome Organization., pp 967-981, In: *Escherichia coli* and *Salmonella typhimurium*, Cellular and Molecular Biology Neidhardt et al., eds, 1987); "By aligning the genetic maps of *E. coli* and *S. typhimurium*, one sees first of all the order of genes on the two maps is nearly identical..." It was further known that there was a high degree of DNA sequence homology, such as the gene *aroF*, which shares 85% nucleic acid homology and 96% amino acid homology between *E. coli* and *Salmonella* (Muday GK, Herrmann KM. Regulation of the *Salmonella typhimurium aroF* gene in *Escherichia coli*. *J Bacteriol*. 1990 May;172(5):2259-66.). Furthermore, in the same study, the *trp* repressor element recognized the regulatory elements equally between both species, further